Some Frequently Asked Questions Concerning NELAC QS (Chapter 5):

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No, QS does not require the use of a specific method/s. Chapter 5 allows the user to select an appropriate method. However, regulatory agencies may mandate the use of a specific method (See also Question 3).

3. Question: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

6. Question: Why are we revisiting the calibration and detection parts of the standards?

Answer: At NELAC IV the Quality Systems Committee received numerous comments that the calibration and detection parts of the standards were too prescriptive and were not consistent with a PBMS environment. The Committee has attempted to propose changes to the calibration and detection parts of the standards that provide essential elements for those two quality system standards and that will support the anticipated needs of PBMS. The Committee believes the proposed language is less prescriptive (i.e., more flexibility), yet hopefully still ensures the quality of the analytical data.

In making these proposed changes the Committee has attempted to balance the need for more flexibility in the standards with the desire to not go to far and introduce excessive flexibility that could prove to be too vague or ill-advised. The Committee is currently discussing and considering its proposed language and public comments on the proposed language changes. The Committee is committed to assuring that the NELAC Quality Systems standards provide a foundation for PBMS implementation.

7. Question: Several States have indicated that it is very desirable that a laboratory already be actively analyzing samples for a particular program and by a method for which they want to be accredited. However, these same states have relayed that this ideal scenario is often not the case, as a laboratory may request accreditation in attempts to expand their scope of analytical services or in order to satisfy contractual requirements. These states ask: How will the QS standards help ensure that laboratories will have sufficient data for an onsite assessment especially given the proposed changes to the MDL section?

Answer: The MDL, section D.1.4, in the 1998 NELAC standards has a requirement that "MDLs" be determined initially (40 CFR Part 136, Appendix B) and be verified yearly by the analysis of at least one clean matrix sample spiked at the current reported MDL. Under the proposed revision to Section D.1.4, "Detection Limits" are to be determined initially and each time there is significant change in the test method or instrument type. The proposed standard still requires "MDL" if required in the mandated test method or applicable regulation. If the MDL is not required a "detection limit" must still be determined. Therefor the new section D.1.4 requirements should still help assure that performance data will be available for review by inspectors . In addition, laboratories are required to successfully complete two out of three PT samples yearly and this data would be available for review, as per section 5.5.4 and Chapter 2) . However, under the current PT requirements this may only include one method of multiple methods employed by a laboratory for a given parameter group, e.g., metals.

Laboratories also must perform an Initial Demonstration of Analytical Capability (5.10.2.1, D.1.3 Method Evaluation and Appendix C) . This data would be available for on-site review. Also note that the QS committee plans to expand Appendix C (IDC) procedures prior to NELAC V to make it applicable to methods for which spiking is difficult or impossible, e.g., Total Suspended Solids, which should further ensure that performance data is available for review.

In addition under Section 5.6.2.3.c. of QS, the Laboratory Management must ensure that the training of personnel is kept up-to-date, which includes a analyst certification to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year: i. acceptable performance of a blind sample (single blind to the analyst); ii. another initial demonstration of method capability; iii. successful analysis of a blind performance sample on a similar test method using the same technology; iv. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; vi if i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable. These requirements should further help assure performance data is available on-site for review.